

**REMARKS**

**I. Status of the Application**

Claims 1, 31-36, 55, and 56 are currently pending before the Examiner. Applicants have amended claim 1 with this response. No new matter is presented by way of this amendment.

Of the pending claims, the Examiner has rejected claim 1 under 35 U.S.C § 102(b) as being anticipated by U.S. Patent No. 5,413,120 (hereinafter “Grant”). Further, the Examiner has rejected claims 55 and 56 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 849,471 (hereinafter “Gamble”). Finally, the Examiner has rejected claims 1 and 31-36 under 35 U.S.C. § 103(a) as being unpatentable under U.S. Patent No. 5,076,289 (hereinafter “Darling”) in view of Grant. As explained below, Applicants respectfully traverse all of these rejections and request withdrawal of the same.

**II. Rejection under 35 U.S.C. § 102(b)**

Claim 1 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Grant. However, Grant does not disclose each and every element of amended claim 1.

Claim 1, as amended, discloses a one piece site guard that covers a site and can be used on any portion of a patient’s body. Specifically, the site guard comprises a hollow member, which has a base with an edge to be positioned upon a patient adjacent a site such that the hollow member covers the site. The base of the hollow member has a width sufficient to straddle the site and a length and a height sufficient to cover the site, the base joined to a sidewall to form a cover. Moreover, the site guard comprises a fabric connector, which is affixed to the hollow member in order to hold the site guard in place over the site.

In contrast, Grant discloses a multi-component catheter shield for use on a patient’s hand or wrist. The multi-component catheter shield comprises “a base and an overlying transparent

shield.” (Col. 2, Ins. 51-53). Particularly, the “base” disclosed by Grant is a “base member dimensioned to underlie a patient’s hand or wrist.” (Col. 2, Ins. 5-9). This base contains “open slots” or “strap receiving slots.” (Col. 3, Ins 5-9). These slots are to accommodate straps, which though not affixed to the base, can be inserted to secure the patient’s hand to the base. (Col. 3, Ins 5-9). Furthermore, Grant discloses a transparent shield that can be placed on top of the base to cover the site. (Col. 3, Ins. 29-45).

Thus, Grant cannot anticipate amended claim 1 because Grant does not disclose a single component site guard for use on any part of a patient’s body. Rather, Grant disclose a multi-component catheter shield for use on a patient’s hand or wrist. Specifically, the catheter shield disclosed in Grant comprises a base, a transparent shield, and straps. These components are not joined together but rather are separate pieces, unlike the site guard disclosed in amended claim 1.

In addition, Grant does not disclose a hollow member comprising a base with an edge to be positioned upon the body part of a patient adjacent a site such that the hollow member covers the site. Grant only discloses a base, which is positioned under the site. Thus, the base as disclosed by Grant cannot and does not cover the site.

Accordingly, Applicants respectfully submit that amended claim 1 is allowable over Grant. It follows that claims 31-36 are also allowable as they depend on amended claim 1.

Claims 55 and 56 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Gamble. However, Gamble does not disclose each and every element of claims 55 and 56.

Claim 55 discloses a site guard for use on intravenous sites as well as other sensitive areas. Particularly, the site guard comprises a hollow member and a fabric connector. The hollow member has a base with an edge to be positioned upon a patient adjacent a site, the base having a width sufficient to straddle the site and a length and a height sufficient to cover the site,

the base joined to a sidewall to form a cover. The fabric connector has a closure means, wherein the connector is capable of holding the hollow member in place over the site without the need for separate adhesive tape.

Similarly, claim 56 discloses a site guard for use on intravenous sites as well as other sensitive areas. Specifically, the site guard comprises a hollow member and a fabric connector. The hollow member has a base with an edge to be positioned upon a patient adjacent a site, the base having a width sufficient to straddle the site and a length and a height sufficient to cover the site, the base joined to a sidewall to form a cover. The fabric connector has a first end and a second end, the first end affixed to the edge of the hollow member and the second end having a closure means, wherein the connector is capable of holding the hollow member in place over the site without the need for a separate adhesive tape.

In contrast, Gamble discloses “abdominal guards and supporters designed more especially for baseball, foot-ball, and polo players, wrestlers, boxers, and the like.” (Ins. 8-12). Specifically, the abdominal guard and supporter of Gamble comprises a “thin sheet of metal” containing “a plurality of ventilating-openings.” The guard and supporter of Gamble has an edge that is “reinforced by strips of canvas or other substantially waterproof fabric, as indicated at 8, these being secured in place by sewing through perforations in the frame, the stitches indicated at 9.” (Ins. 41-46). The abdominal guard and supporter is held in place with straps “or tape.” (Ins. 46-47).

Consequently, Gamble does not disclose the site guard of either claim 55 or claim 56 as Gamble does not disclose a site guard comprising a hollow member and a fabric connector that is capable of holding the hollow member in place over the site *without* the need for a separate adhesive tape. Gamble specifically teaches the use of adhesive tape. Moreover, the fabric that is

disclosed in Gamble is not used to hold the hollow member in place. Rather, the fabric acts as a moisture-proof padding at the edge of the abdominal guard and supporter.

Hence, for the reasons outlined above, Applicants respectfully submit that claims 55 and 56 allowable over Gamble.

**III. Rejection under 35 U.S.C. § 103(a)**

As set forth above, claims 1 and 31-36 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Darling in view of Grant. However, it is respectfully submitted that the Examiner has failed to make a *prima facie* case of obviousness with regard to claims 1 and 31-36 because neither Darling nor Grant, alone or in combination, disclose or suggest the presently claimed invention.

The Pending Application discloses a multi-purpose site guard for use on all types of patients at all peripheral and central vein puncture infusion sites and sensitive areas. Further, the site guard disclosed in the Pending Application comprises two basic components, a hollow member and a fabric connector. The hollow member comprises a base with an edge to be positioned upon a patient adjacent a site such that the hollow member covers the site, the base having a width sufficient to straddle the site and a length and a height sufficient to cover the site, the base joined to a sidewall to form a cover. In addition, affixed to the hollow member is a fabric connector which holds the site guard in place over the site.

In contrast, Darling discloses a means of supporting the attachment of an intravenous (“I.V.”) line to a patient. (Col. 1, Ins. 5-9). Specifically, Darling discloses a support means with one basic component, “an integral fabric wrap.” (Col. 3, Ins. 48-53 and Fig. 1). For the support means to function, the I.V. line is looped around a patient’s thumb, the patient’s thumb is inserted through a slit in the support means, and the support means is then wrapped around the

patient's hand. (Col. 3, lns. 38-54). An objective of the invention disclosed in Darling is to "provide support means for I.V. lines and the like which enhance the freedom of movement and manual capacity for patients attached to such IV lines." (Col. 2, lns. 13-16).

Consequently, Darling does not teach or suggest the Pending Application. Darling does not teach or suggest a site guard comprising a hollow member and a fabric connector. Darling also does not teach or suggest the use of a site guard on any portion of a patient's body. Nor, does Darling teach or suggest a device which covers infusion sites or sensitive areas. Darling only teaches and suggests a device that is directed at attaching an I.V. line to a patient. In light of the above, amended claim 1 is allowable as the site guard disclosed in the Pending Application is not obvious under Darling.

The site guard disclosed in the Pending Application is also not obvious even when Darling is combined with Grant. Nothing in Grant teaches or suggests a hollow member with a base having an edge to be positioned upon the body part of a patient adjacent a site such that the hollow member covers the site. Rather, the base in Grant is placed under the site. Moreover, Grant does not teach or suggest a hollow member that is affixed to a fabric connector. Instead, Grant discloses a base which contains open slots to accommodate straps. Furthermore, unlike the site guard disclosed in the Pending Application, the straps in Grant hold only the base to the patient, and not the entire site guard to the patient. For all of the aforementioned reasons, the Pending Application is not obvious even if Darling is combined with Grant. Thus, amended claim 1 is allowable.

There is, however, no suggestion to combine these references. In fact, the references themselves teach away from making such a combination. Specifically, while Darling teaches a device to enhance a patient's freedom of movement, Grant teaches the exact opposite. Grant

teaches a device which "immobilizes a patient's hand and fingers." (Col. 2, Ins. 34-35).

Consequently, one skilled in the art would not combine Darling with Grant.

In addition, even if one skilled in the art combined Darling with Grant, such a combination would not achieve the same results as the Pending Application. Thus, because a combination of Darling and Grant does not render obvious the site guard disclosed in the Pending Application, amended claim 1 is allowable. Claims 31-36 are also not obvious and are allowable as they depend on amended claim 1.

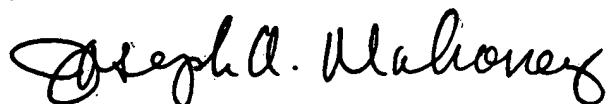
**IV. Conclusion**

With entry of the above amendment and in view of the foregoing remarks, it is respectfully submitted that claims 1, 31-36, 55 and 56 are in condition for allowance.

None of Applicants' amendments or cancellations are to be construed as dedicating any such subject matter to the public, and Applicants reserve all rights to pursue any such subject matter in this or a related patent application.

It is respectfully submitted, in view of the foregoing Amendment and Remarks, that all of the objections and rejections in the Office Action dated December 13, 2004 have been overcome and should be withdrawn. Applicants respectfully request early and favorable notification to that effect. The Examiner is encouraged to contact the undersigned with any questions or to otherwise expedite prosecution

Respectfully submitted,



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